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Remarks

Claims 1-35 were pending in the subject application. By this Amendment, the applicants have amended claims 1, 10, 19, 31, and 35. No new matter has been added by these amendments. Support for the amendments to the claims can be found throughout the subject application including, for example, at page 7. Accordingly, claims 1-35 are now before the Examiner for consideration.

The amendments set forth herein should not be interpreted to indicate that the applicant has agreed with, or acquiesced to, the objection set forth in the outstanding Office Action. The amendments to the claims have been made in an effort to lend greater clarity to the claimed subject matter and to expedite prosecution. Favorable consideration of the claims now presented, in view of the remarks and amendment set forth herein, is earnestly solicited.

The drawings have been objected to under 37 CFR 1.83(a). The applicants appreciate the Examiner's careful review of the specification and drawings. The Examiner has requested that the spokes and ridges in the circle-C and double-D configurations as cited in the claims and the specification be indicated on the figures. In addition, the Examiner has requested an illustration of the catheter as situated in superior vena cava and right atrium (as recited in claim 32). Therefore, new Figures 9 and 10 are being submitted herewith that include the ridges (indicated reference numeral 70) and spokes (indicated reference numeral 75) as well as location of the catheter in the right atrium (indicated reference numeral 100) and superior vena cava (indicated reference numeral 105). In addition, the specification has been amended to account for the new figures and reference numerals. The applicants respectfully assert that no new matter has been added to with these new figures and respectfully request that they be approved and included in the application.

The present invention provides a unique catheter for use during dialysis. As recited in the claims, a catheter is provided that functions primarily in "reverse-flow," having a dual lumen configuration (*i.e.*, co-axial, circle C, double D, and side-by-side configurations) in which the arterial lumen extends beyond the termination point of the venous lumen. Further, the arterial lumen is disposed within the venous lumen. According to the subject invention, the arterial lumen is utilized to remove blood from the patient's vasculature while the venous lumen is utilized to return treated blood to the patient. The return of blood through the second/venous lumen allows for high flow/high

pressure return of blood proximal to the first/arterial lumen, thereby preventing or reducing the likelihood of fibrin sheath forming around the distal end of the first/arterial lumen. This reduction in fibrin sheath formation allows for improved catheter flow rates for longer periods of time than those generally observed with conventional catheters. Despite the rejections set forth in the outstanding Office Action, no one has taught the dual-lumen catheters having an arterial lumen that extends beyond the termination point of the venous lumen for use in dialysis as recited in the current claims, nor has this catheter even been suggested.

Claims 1, 2, 8, 24, 25, 27-31 and 33 have been rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,718,678 (Flemming). The applicant respectfully traverses this ground for rejection because the Flemming reference neither teaches nor suggests the currently claimed catheter and its method of use.

In support of his traversal, the applicant respectfully submits that the Flemming reference did not teach a dual lumen catheter having an arterial lumen that extends beyond the termination point of the venous lumen for use in dialysis. The office action relies in particular on excerpts from Flemming at column 5, lines 1-30. However, the applicant respectfully notes that the teachings of the reference as a whole must be considered, and in their proper contexts, to provide proper basis for the rejection. The applicant respectfully asserts that the cited sections of the Flemming specification have been taken out of context and combined in a manner not consistent with the teachings of the reference.

Specifically, col. 1, lines 5-9, col. 2, lines 66-67 and col. 3 lines 1-3, and col. 4, lines 60-64, as well as claim 1, all begin with Flemming reciting that his catheter has three lumens. Note that Flemming describes a triple lumen catheter, "but could include four or more lumens depending upon the physical constraints of the catheter size and the structural integrity necessary for forming the catheter tubes." See col. 12, lines 10-14. Clearly, the intent of this sentence is to indicate that the Flemming catheter is to have at least three, if not more, lumens. Nowhere in the Flemming reference is there a teaching or suggestion for a dual lumen catheter having an arterial lumen that extends beyond the termination point of the venous lumen.

Further, in contradistinction to the arguments set forth on pages 3-5 of the office action, Flemming merely describes placement of catheters as known to the skilled artisan, in the right subclavian vein or right or left internal jugular vein (see col. 1, lines 14-16). His own examples do not describe the specific placement of the arterial lumen in a right atrium and the venous lumen in a superior vena cava. In no instance does Flemming indicate how a triple lumen catheter might be positioned in such a fashion. Thus, it is quite clear that Flemming does not teach the use of his multi-lumen catheter as recited in the current claims.

It is basic premise of patent law that, in order to anticipate, a single prior art reference must disclose within its four corners, each and every element of the claimed invention. In *Lindemann v. American Hoist and Derrick Co.*, 221 USPQ 481 (Fed. Cir. 1984), the court stated:

> Anticipation requires the presence in a single prior art reference, disclosure of each and every element of the claimed invention, arranged as in the claim. *Connell v. Sears Roebuck and Co.*, 220 USPQ 193 (Fed. Cir. 1983); *SSIH Equip. S.A. v. USITC*, 216 USPQ 678 (Fed. Cir. 1983). In deciding the issue of anticipation, the [examiner] must identify the elements of the claims, determine their meaning in light of the specification and prosecution history, and identify corresponding elements disclosed in the allegedly anticipating reference. *SSIH, supra; Kalman v. Kimberly-Clarke*, 218 USPQ 781 (Fed. Cir. 1983) (emphasis added). 221 USPQ at 485.

In *Dewey v. Almy Chem. Co. v. Mimex Co.*, Judge Learned Hand wrote:

> No doctrine of the patent law is better established than that a prior patent . . . to be an anticipation must bear within its four corners adequate directions for the practice [of the subsequent invention] . . . if the earlier disclosure offers no more than a starting point . . . if it does not inform the art without more how to practice the new invention, it has not correspondingly enriched the store of common knowledge, and it is not an anticipation. 52 USPQ 138 (2nd Cir. 1942).

As noted above, the Flemming reference does not disclose or suggest a dual-lumen dialysis catheter in which the arterial lumen extends beyond the termination point of the venous lumen. Nor does Flemming teach or suggest placing the catheter in a patient, wherein the arterial lumen is situated in the right atrium of a patient's heart and the venous lumen is situated in the superior vena cava. Thus, under the applicable statutory and case law, the Flemming reference does not anticipate

the applicant's claims. Therefore, reconsideration and withdrawal of the rejection under 35 USC §102(b) is respectfully requested.

Next, the applicant respectfully traverses the §103 rejections of claims set forth at pages 5-13 of the office action. The deficiencies of the Flemming reference have been noted above, and are reasserted here. With regard to claims 6, 7 and 26, U.S. Patent No. 6,595,966 (Davey *et al.*) is cited as a secondary reference. While Davey *et al.* describes tapering a catheter at a distal portion, neither Flemming nor Davey *et al.* teaches a dual-lumen dialysis catheter in which the arterial lumen extends beyond the termination point of the venous lumen. Further, neither reference teaches use of a dual-lumen catheter wherein the arterial lumen is placed in a right atrium and venous lumen is placed in a superior vena cava. Thus, the deficiencies of Flemming are not cured.

Regarding the rejections of claims 11-14, the secondary reference is U.S. Patent No. 5,167,623 (Cianci *et al.*). The deficiencies of the Flemming reference have been noted above in detail and are not cured by the Cianci *et al.* reference. The Cianci *et al.* catheter is very similar to that of the Flemming catheter in that it is a multi-lumen catheter and not a dual-lumen catheter (see, for example, col. 1, lines 6-7, col. 2, lines 14-22, and col. 2, lines 51-64 as well as claim 1 and Figure 1A). As with Flemming, the Cianci *et al.* reference fails to teach a dual lumen catheter having an arterial lumen extends beyond the termination point of the venous lumen. Thus, the deficiencies of the Flemming reference are not cured.

With regard to claims 18 and 19, the secondary references are U.S. Patent No. 5,167,623 (Cianci *et al*). and U.S. Patent No. 6,206,849 (Martin *et al.*). The shortcomings of the Flemming and Cianci *et al.* references are not cured by Martin *et al.* Again, as with the Flemming and Cianci *et al.* references, the Martin *et al.* reference describes a multi-lumen catheter and not a dual-lumen catheter (see, for example, claim 1 "A triple lumen catheter...." Emphasis added). As with Flemming and Cianci *et al.*, the Martin *et al.* reference fails to teach a dual lumen catheter having an arterial lumen extends beyond the termination point of the venous lumen. Thus, the deficiencies of the Flemming and Cianci *et al.* references are not cured by Martin *et al.*

Claims 15 and 16 have been rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,718,678 (Fleming) in view of U.S. Patent No. 5,167,623 (Cianci *et al.*), further in

view of U.S. Patent No. 6,595,966 (Davey *et al.*). As described in detail above, neither the Flemming nor the Cianci *et al.* and Davey *et al.* references describe a dual lumen dialysis catheter having an arterial lumen that extends beyond the termination point of the venous lumen. Because the deficiencies of the Flemming and Cianci *et al.* references are not cured by Davey *et al.*, a finding of obviousness is not proper based on Flemming in view of Cianci *et al.* and Davey *et al.*

Claims 9, 10 and 20-23 have been rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,718,678 (Fleming) in view of U.S. Patent No. 6,206,849 (Martin *et al.*). As described in detail above, neither the Flemming nor the Martin *et al.* references describe a dual lumen dialysis catheter having an arterial lumen that extends beyond the termination point of the venous lumen. Because the deficiencies of the Flemming references are not cured by Martin *et al.*, a finding of obviousness is not proper based on Flemming in view of Martin *et al.*

Regarding claim 32, the secondary reference is U.S. Patent No. 6,620,118 (Prosl *et al.*). The Prosl *et al.* reference describes the use of two separate catheters for performing dialysis, wherein a return line is situated in the superior vena cava and the suction line is situated in the right atrium (see col. 25). There is no description by Prosl *et al.* regarding a dual-lumen catheter having an arterial lumen that extends beyond the termination point of the venous lumen, wherein the arterial lumen is situated in the venous lumen. Thus, the deficiencies of the Flemming reference are not cured by Prosl *et al.*

Finally, regarding the rejection of claim 34, the secondary reference is U.S. Patent No.6,719,749 (Schweikert *et al.*). As with Prosl *et al.* and specifically noted in the Office Action, Schweikert *et al.* describes two separate catheters for performing dialysis (see page 12, last paragraph of the Office Action). It teaches nothing about a dual lumen dialysis catheter having an arterial lumen that extends beyond the termination point of the venous lumen, wherein the arterial lumen is situated in the venous lumen; and thus fails to cure any of the shortcomings of Flemming.

A finding of obviousness is proper only when the prior art contains a suggestion or teaching of the claimed invention. Here, it is only the applicant's disclosure that teaches a dual lumen catheter having an arterial lumen that extends beyond the termination point of the venous lumen for use in dialysis, and the applicant's disclosure cannot be used to reconstruct the prior art for a

rejection under 35 U.S.C. §103. This was specifically recognized by the CCPA in *In re Sponnoble*, 160 USPQ 237, 243 (1969):

> The Court must be ever alert not to read obviousness into an invention on the basis of the applicant's own statements; that is we must review the prior art without reading into that art appellant's teachings. *In re Murray*, 112 USPQ 364 (1959); *In re Sprock*, 133 USPQ 360 (1962). The issue, then, is whether the teachings of the prior art would, in and of themselves and without the benefits of appellant's disclosure, make the invention as a whole, obvious. *In re Leonor*, 158 USPQ 20 (1968). (Emphasis in original)

The mere fact that the purported prior art could have been modified or applied in a manner to yield applicant's invention would not have made the modification or application obvious unless the prior art suggested the desirability of the modification. *In re Gordon*, 221 USPQ 1125, 1127 (Fed. Cir. 1984). Moreover, as expressed by the CAFC, to support a §103 rejection, "[b]oth the suggestion and the expectation of success must be founded in the prior art . . . ." *In re Dow Chemical Co.*, 5 USPQ 2d 1529, 1531 (Fed. Cir. 1988). In the Flemming and secondary references, one finds neither. Because the deficiencies of the Flemming reference have not been cured by any of the secondary references relied on in the office action, the obviousness rejections set forth at pages 5-13 should be withdrawn.

The applicant respectfully submits that any suggestion to a dual lumen catheter having an arterial lumen that extends beyond the termination point of the venous lumen for use in dialysis could only be arrived at through hindsight reconstruction, which is improper. Accordingly, reconsideration of the obviousness rejections set forth at pages 5-13 is respectfully requested.

In view of the foregoing remarks and the amendments above, the applicant believes that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 CFR §§1.16 or 1.17 as required by this paper to Deposit Account No. 19-0065.

The applicant also invites the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephone interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,

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Attachments: New Sheets for Figures 9 and 10